BIONOSTICS
Quality Solutions

K131136

510(k) Summary[1]

MAY 3 1 2013

(a) (1) **Submitter's name, address**

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Randy Byrd
VP, Chief Technical Officer
(978) 862-1830

Date of preparation of this summary: 30 May 2013

(2) Device trade or proprietary name: Glucose Meter-Check® Solution for TaiDoc

Device common or usual name or classification name:

75 JJX, single (specified) analyte controls (assayed and unassayed)

	CLASSIFICATION		
PRODUCT NOMENCLATURE	**NUMBER**	**CLASS**	**PRODUCT CODCE**
Quality Control Material	862.1660	I,reserved	JJX

(3) Substantial Equivalence

This quality control material is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use:

	Fora, TaiDoc Control Solutions (GOD & GDH)	**Glucose Meter-Check for TaiDoc (GOD & GDH)**
510(k), date	K093724 07.29.2010	
Net Fill	4 mL	same
Intended Use	The FORA Glucose Control Solution and Taidoc Glucose Control Solution are intended for in vitro diagnostic use (i.e. for external use only) to assess the performance of the blood glucose test meters and test strips manufactured by Taidoc Technology Corporation by healthcare professionals and in the home by people with diabetes mellitus.	Glucose Meter-Check Solution for TaiDoc is intended for in vitro diagnostic use (i.e., for external use only) to assess the performance of blood glucose meters and test strips manufactured by TaiDoc Technology Corporation by healthcare professionals and in the home by people with diabetes mellitus
Color	red	same
Analyte	d-glucose	same
Container	6 mL LDPE vial with dispensing tip and cap	same
Matrix	buffered, aqueous solution with salts, viscosity modifier, preservatives and other non-reactive ingredients	same

[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

	Fora, TaiDoc Control Solutions (GOD & GDH)			Glucose Meter-Check for TaiDoc (GOD & GDH)		
Auto QC detection	No			same		
Levels	3			3		
Enzyme Type		GOD	GDH		GOD	GDH
Target Ranges	Low:	60 – 80	35 – 65	1:	60 – 80	35 – 65
	Normal:	100 – 150	112 – 168	2:	100 – 150	112 – 168
	High:	250 - 350	224 – 336	3:	250 - 350	224 – 336

Table 5.1: Summary of Equivalent Characteristics

(4) Description of the new device

The control solutions are comprised of buffered aqueous liquid glucose control solution with viscosity modifiers to simulate certain properties of blood on the test strip and colored red to help users see the solution while dispensing onto a test strip. The control solutions are formulated to have performance comparable to those currently manufactured by TaiDoc Technology Corporation. The product is packaged in plastic bottles with dropper tips for dispensing the control solutions for use with test strips.

This is a non-hazardous aqueous glucose control solution containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation.

Standard/Guidance Documents Referenced (if applicable):

- ISO 15197:2003 In Vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2009 Medical devices – Application of risk management to medical devices
- ISO 13485:2007 Medical Devices – Quality Management Systems – Requirements for regulatory purposes
- ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
- ISO 18113-4 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 4: In vitro diagnostic reagents for self-testing
- EN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

(5) Intended use of the device

Glucose Meter-Check Solution for TaiDoc is intended for in vitro diagnostic use (i.e., for external use only) to assess the performance and correct operation of blood glucose meters and test strips manufactured by TaiDoc Technology Corporation by healthcare professionals and in the home by people with diabetes mellitus.

(6) Technological characteristics of the device.

This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a single concentration of d-glucose and has been optimized to simulate the response of whole blood on the relevant blood glucose test systems. The solution contains no hazardous, human or animal derived components. The analyte, d-glucose, is the same as detected by the blood glucose monitoring systems for which this control is intended.

Test Principle

The BGMS with which this control solution is utilized all measure glucose concentration electrochemically in whole blood through enzymatic reactions utilizing glucose oxidase or glucose dehydrogenase enzymes.

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Analytical performance

a) Traceability, stability, expected values (controls, calibrators, or methods)

Traceability

Glucose concentration is confirmed utilizing YSI-supplied calibrators traceable to NIST SRM 917.

Stability

Closed bottle stability

Stability characteristics were determined under un-opened conditions in real time stability studies on three lots of equivalent product to demonstrate an unopened shelf-life of 2 years (24 months) at the recommended storage temperatures, ranging from 15°C to 30°C (59°F to 86°F) as measured by YSI 2300 calibrated with N.I.S.T. 917 traceable materials.

Stability after opening

Glucose Meter-Check Solution for TaiDoc meets stability requirements as demonstrated by less than 5% change in percent glucose recovery on YSI on vials from a single lot evaluated over 3 months (93 days in real time) stored at ambient temperature ranging from 21 to 23 °C (70 to 75 °F) in comparison to vials of the same product stored at 2-8 °C.

Value assignment

Value assignment for each lot of product is determined as the mean of measurement on each lot and level of control solution determined from measurement of 8 samples on each of 5 meters with three lots of commercially distributed test strips for a total of 120 measurements. Value assignment range is determined as the mean of all measurements ±15 mg/dl (glucose < 80 mg/dL) or ± 15% (glucose ≥ 80 mg/dL).

Expected values / Reference Range

The expected values for the Glucose Meter-Check for TaiDoc controls are provided on each vial of control solution.

Proposed Labeling

We have provided labeling with this submission which is sufficient and satisfies the requirements of 21 CFR Part 809.10.

(b) (2) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2013

Bionostics, Inc.
C/O Mr. Randy Byrd
7 Jackson Road
DEVENS MA 01434

Re: K131136
Trade/Device Name: Glucose Meter-Check Solution for TaiDoc
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJX
Dated: April 19, 2013
Received: May 01, 2013

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131136

Device Name: Glucose Meter-Check Solution for TaiDoc

Indications For Use:

Glucose Meter-Check Solution for TaiDoc is intended for in vitro diagnostic use (i.e., for external use only) to assess the performance of blood glucose meters and test strips manufactured by TaiDoc Technology Corporation by healthcare professionals and in the home by people with diabetes mellitus. For In Vitro Diagnostic Use

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Katherine Serrano

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)